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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,715	03/03/2004	Gregory M. Glenn	056707-5001-01	4303

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EXAMINER

KIM, YUNSOO

ART UNIT PAPER NUMBER

1644

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,715

Applicant(s)

GLENN ET AL.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

5-0-0

DETAILED ACTION

1. Claims 1-70 have been canceled.
Claims 71-105 have been added.
Claims 71-105 are pending.
2. Applicant's species election with traverse in the reply filed on 6/1/05 is acknowledged.
Upon Applicants' cancellation and addition of new claims, the species election has withdrawn.
3. Applicants' IDS filed on 3/3/04 is acknowledged. However, the foreign documents and non-patent literatures on p. 8-14 (except the references on p.8) have not been considered because the copies of references were not available to examiner. Also, Y89 and Y90 of p.19 have been crossed out as being duplicates of gl and gr of p. 7.
4. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The instant claims may not have the benefit under 35 U.S.C. 120 of all the parent filing dates. The subject matter claimed in claims 71 and 78-85 are supported in the parent application USSN 09/257,188 on 2/25/99 and the filing dates of claims 72-77 and 86-105 is deemed to be the filing date of the instant application as the parent application does not support the claimed limitations of the instant application. If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the parent application.
5. The application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a) (2). However, this application fails to comply with the requirements of 37 CFR 1.821-1.825. Specifically, the sequences on p. 50 and 59 of the specification must be brought into sequence compliance and identified by SEQ ID NOs.
6. The following is a quotation of the second paragraph of 35 U.S.C.112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1644

The term "sufficient" in claims 71 and 86 is a relative term which renders the claim indefinite. The term "sufficient" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 72-77 and 86-100 are rejected under 35 U.S.C.112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- a) "only the outer surface of said area of skin" (claims 72, 87, 90, 94 and 95)
- b) pretreating with one or "more" chemicals and "combinations thereof" (claims 73, 74, 88 and 98)
- c) "emory board" (claims 76 and 100)
- d) "concurrently" (claims 86 and 96)

Applicant's amendment filed on 6/1/05 asserts that no new matter has been added, however, specific terms or phrases in support of the new amendments to the claims have not been found by the Examiner as indicated by the Applicants.

Applicants are required to cancel the new matter in the response to this Office Action. Alternatively, Applicants are invited to provide clearly point out the written support for the instant limitations.

Art Unit: 1644

9. Claims 71-105 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inducing an antigen specific immune response comprising pretreating with detergent and applying a formulation comprising a CT, LT HA as an antigen and ADP-ribosylating exotoxin as an adjuvant, does not reasonably provide enablement for any methods for inducing an antigen specific immune response comprising any formulation comprising any antigen, any adjuvants and pretreating skin with any penetration enhancer, such as alcohol or device comprising tines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not reasonably provide enablement for any method of inducing an immune response comprising pretreating with any penetration enhancers and applying a formulation comprising any antigen and any adjuvant.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

There is insufficient guidance in the specification as filed as to how the skilled artisan would use penetration enhancer other than detergent to induce immune response to achieve the intended use of the claimed invention without undue experimentation.

As acknowledged in 5,980,898 patent, col. 5, lines 38-45, Applicants does not include alcohols as a source of penetration enhancer because alcohols would not perforate the skin. Furthermore, Applicants have no working examples demonstrating the pretreating with the device comprising tines enhance the immune response.

Art Unit: 1644

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the breadth of the claims. The antigen includes any bacteria, viruses, parasites or fungi and the adjuvants include any bacterial toxins, lipids, any cytokines, or chemokines. However, it is noted in examples 7 and 10, diphtheria toxin (DT) does not function as an adjuvant as in claimed methods.

Thus, Applicant has not provided any guidance to enable one skill in the art to use claimed invention in manner reasonably correlated with the scope of enablement. In view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 71-105 are provisionally rejected under the judicially created doctrine of double patenting over pending claims 1-11 of copending U.S.Pat. No. 6,797,276 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising an antigen and an adjuvant to skin.

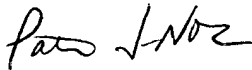
12. No claims are allowable.

Art Unit: 1644

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
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June 29, 2005


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